

REMARKS

Claims 1-22 are pending in the subject application. Claims 1 and 19 are amended, claim 23 is canceled, and claim 24 is added. Applicants submit that the amendments herein introduce no new matter, support therefore being found throughout the application and drawings as originally filed.

The Applicants appreciate the Examiner's thorough examination of the subject application and request reconsideration based on the amendments and the following remarks.

1. 35 U.S.C. §102 Rejections

Claim 1 is rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,725,493 to Avery et al. (hereinafter "Avery"). Applicants respectfully traverse.

Applicants recite, in amended claim 1, a subretinal delivery device comprising a reservoir and a cannula extending from the reservoir, wherein an agent in the reservoir is released through the cannula to the eye subretinally. As set out, the cannula is configured to have a length that extends from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye.

Avery, on the other hand, describes a device and method for intravitreal medicine delivery. In particular, Avery provides a housing 80 that is positioned on the outer surface of an eyeball with a tube 140 extending from the housing 80 along the outer surface of the eyeball. The tube 140 is described as an extension of the reservoir that, together with the reservoir, constitute one large external storage reservoir or chamber (col. 6, lines 19-24). A tubular elbow 160 is attached to the distal end of the tube 140 and includes an intravitreal extension 164 that projects at an angle so as to be insertable within the eye (see col. 6, line 34-46; col. 6, line 58 – col. 7, line 22).

Medicine in the reservoir is thereby released through the intravitreal extension into the vitreous cavity.

Clearly, Avery does not teach or suggest a subretinal delivery device. Further, Avery does not teach such a device having a cannula configured to have a length that extends from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. Rather, Avery provides a device wherein the housing 80 is positioned on the outer surface of the eyeball under the conjunctiva and Tenon's capsule with the preformed tube 140 having rigidity extends along the outer surface of the eye to the pars plana (col. 6, lines 56-67). The elbow 160 extending at an angle from the tube 140 directs the intravitreal extension 164 of the elbow through a hole in the eyeball into the vitreous where the tip 166 of the intravitreal extension 164 terminates to deliver medicine to the vitreous (see e.g. col. 7, lines 1-5; Figs. 2, 4, 6).

Accordingly, it is respectfully submitted that claim 1 is patentable over Avery. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §103 Rejections

Claims 2-18 and 23 are rejected under 35 U.S.C. §103(a) over Avery and U.S. Patent No. 5,454,796 to Krupin (hereinafter "Krupin") or U.S. Patent No. 5,370,607 to Memmen (hereinafter "Memmen"). Applicants respectfully traverse.

As set forth above, claim 1 is are not taught or suggested by Avery. Further, neither Krupin nor Memmen remedy the above-noted deficiencies in Avery.

Krupin describes a drainage device and method for lowering intraocular pressure in the eye by draining fluid from the anterior chamber of the eye. Krupin's device includes an oval shaped plate 12 with an attached elongate tube 14. The plate 12 is configured so as to nest on the outer surface of the eye between adjacent rectus

muscles of the eye, and the tube 14 is configured to extend from the plate 12 into the anterior chamber of the eye to drain fluid from the anterior chamber of the eye through the tube 14 into the plate 12.

Clearly, Krupin does not teach or suggest a subretinal delivery device. Further, Krupin does not teach or suggest such a device having a cannula configured to have a length that extends from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. This teaching comes purely from Applicants' disclosure.

Like Krupin, Memmen describes a device and method for treating glaucoma by draining fluid out of the anterior chamber of the eye. Memmen's device includes a reservoir 20 configured so as to be positionable along the outer surface of an eyeball, and a drainage tube 60 configured to extend from the reservoir 20 into the anterior chamber of the eye such that fluid can be withdrawn from the anterior chamber of the eye through the tube drainage tube 60 into the reservoir 20.

Clearly, Memmen does not teach or suggest a subretinal delivery device. Further, Memmen does not teach or suggest such a device having a cannula configured to have a length that extends from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. This teaching comes purely from Applicants' disclosure.

Thus, clearly no combination of Avery, Krupin, and Memmen would provide Applicants' subretinal delivery device and methods of treatment.

Accordingly, it is respectfully submitted that claim 1 is patentable over Avery, Krupin, and Memmen. Claims 2-6, 8-18 depend from claim 1 and, thus, also are

patentable over Avery, Krupin, and Memmen. Claim 23 is canceled herein, without prejudice, and thus rejection of this claim is moot. Reconsideration and withdrawal of the rejection is respectfully requested.

Applicants' new claim 24 recites a subretinal delivery device comprising a reservoir and a cannula extending from the reservoir, wherein an agent in the reservoir is released through the cannula to the eye subretinally. As set out, the cannula is configured extend from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. Further, the cannula has a pointed distal end for insertion through the retina, the distal end and cannula having a cross-sectional size to allow for disposal in the subretinal space between the retina and choroid of the eye.

As set out above, Avery provides a housing 80 is positioned on the outer surface of the eyeball under the conjunctiva and Tenon's capsule, a preformed tube 140 having rigidity extending along the outer surface of the eye to the pars plana, an elbow 160 extending at an angle from the tube 140 so as to direct the intravitreal extension 164 of the elbow through a hole in the eyeball into the vitreous where the tip 166 of the intravitreal extension 164 terminates to deliver medicine to the vitreous (see e.g. col. 7, lines 1-5; Figs. 2, 4, 6).

Nowhere does Avery teach or suggest a subretinal delivery device. Avery further does not teach or suggest such a device having a reservoir and a cannula extending from the reservoir, wherein the cannula is configured extend from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. Further, Avery nowhere does Avery not teach a cannula having a pointed distal end for insertion through the retina, the distal end and cannula having a cross-sectional size to allow for disposal in the subretinal space between the retina and choroid of the eye. Neither Krupin nor Memmen remedy these deficiencies. Neither Krupin nor Memmen

teach or suggest a subretinal delivery device. Neither Krupin nor Memmen teach or suggest a device having a reservoir and a cannula extending from the reservoir, wherein the cannula is configured extend from the reservoir through the vitreous and through the retina into a subretinal space when the reservoir is disposed exterior the eye on the sclera or when the reservoir is disposed within the eye. Neither Krupin nor Memmen teach or suggest a cannula having a distal end and cannula having a cross-sectional size to allow for disposal in the subretinal space between the retina and choroid of the eye.

Thus, it is respectfully submitted that claim 24 is patentable over Avery, Krupin, and Memmen.

CONCLUSION

In view of the forgoing, Applicants believe the pending application is in condition for allowance. Early and favorable action is requested.

If for any reason a fee is required, a fee paid is inadequate or credit is owed for any excess fee paid, you are hereby authorized and requested to charge Deposit Account No. **04-1105**.

Dated: January 27, 2009

Respectfully submitted,

By /Lisa Swiszc Hazzard/

Lisa Swiszc Hazzard
Registration No.: 44,368
EDWARDS ANGELL PALMER & DODGE
LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 517-5512
Attorneys/Agents For Applicant